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APPLICATION NUMBER 087785,532	FILING DATE 01/17/97	FIRST NAMED APPLICANT GRAY	ATTORNEY DOCKET NO. J 023070-06891
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HM12/0628

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EXAMINER DAVIS III	
ART UNIT 1642	PAPER NUMBER 17

DATE MAILED:

06/28/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/22/99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 2 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-63 is/are pending in the application.

Of the above, claim(s) 1-25, 41-47 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 26-40, 48-63 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_, is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Art Unit: 1642

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following rejections are withdrawn: 1) Rejection under 112, second paragraph of claims 26-40, 48-63 in view of applicant's amendment, and 2) Rejection under 102(e) of claims 26, 56, and 61-63 as being anticipated by Stokke et al, in view of applicant's arguments.

The following are the remaining rejections.

#### **PTO 1449**

A copy of PTO 1449, which was sent to applicant on 09/09/97, is included in this instant Office action.

#### **RESTRICTION**

Applicant further requests reconsideration of the final restriction. Applicant argues that the search for both groups I-II would not cause serious burden for the Examiner, especially in view of the fact that the Examiner has already issued a substantive Office action directed to both of these two groups.

Art Unit:

After reconsideration, applicant arguments are not found persuasive for the following reasons: Restriction requirement is not based solely on the burden on the Examiner. Rather, the restriction requirement is based also on difference in structure of different recited sequences on the generic claim 26, and thus difference in criteria for success of the claimed method. The restriction requirement of the previous Office action on September 7, 1997 was an oversight and should be corrected.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 26-40, 48-63 are being examined.

#### **REJECTION UNDER 35 USC 102**

Rejection under 35 USC 102 of claims 26, 56 and 61-63 pertaining to anticipation by Morris et al remains for reasons already of record in paper No. 14.

Applicant argues as follows:

Every element of the rejected claims is not identically shown in Morris et al. Morris et al do not teach a step of determining increased copy number of nucleic acid sequences at chromosomal region 20q13.2. Morris et al do not even mention chromosome 20.

It is unclear what portion of the probe taught by Morris et al is 88% similar to SEQ ID NO: 9. Thus it is unclear that the probe of Morris et al would inherently hybridize to SEQ ID NO: 9 from 20q13.2. Furthermore the present claims are not directed to a probe, but to a method.

Art Unit:

Applicant's arguments set forth in paper No.16 have been considered but are not deemed to be persuasive for the following reasons:

A portion of the probe taught by Morris et al (from nucleotide number 86498 to 86778) is 88% similar to the SEQ ID NO:9 from nucleotide number 7427 to 7708, as shown by MPSRCH sequence search, from the copy entitled US-08-731-499-9-05, rge. A copy of said search was sent to applicant on the Office action on September 7, 1997. An extra copy of said search is enclosed in the instant Office Action.

The method taught by Morris et al is the same as the claimed method, i.e. hybridization of a probe to a sample, wherein said probe would selectively hybridize to SEQ ID NO: 9 from 20q13.2. Although Morris et al do not mention chromosome 20, the cancerous sample taught by Morris et al would inherently contain chromosome 20. Thus hybridization to SEQ ID NO:9 on chromosome 20 by the probe taught by Morris et al would inherently occur, because the probe taught by Morris et al is 88% similar to SEQ ID NO:9. Furthermore, although Morris et al do not mention determining an increased copy number of nucleic acid sequences at chromosomal region 20q13.2, the method taught by Morris et al would inherently show an increased copy number of nucleic acid sequences at chromosomal region 20q13.2, because the probe by Morris et al would inherently hybridize to an increased copy number of SEQ ID NO:9 present on region 20q13.2.

**REJECTION UNDER 35 USC 112 FIRST PARAGRAPH, ENABLEMENT**

Art Unit:

Claims 26-40, 48-63 are rejected under 35 USC 112, first paragraph as the specification fails to provide an enabled disclosure of a method for screening any neoplastic cells, as set forth in the previous office action of paper No. 14.

Applicant argues as follows:

One of skill in the art can test any biological sample and determine if the sample contains cells having an increased copy number of nucleic acid sequences at region 20q13.2, because applicant discloses the probes, and assays, such as in situ hybridization or southern blots.

Applicant's arguments set forth in paper No. 16 have been considered but are not deemed to be persuasive for the following reasons:

Although one of skill in the art can test any biological sample and determine if the sample contains cells having an increased copy number of nucleic acid sequences at region 20q13.2, the increased copy number of SEQ ID NO:9 does not mean that any cancer, including ovarian, bladder and colorectal tumor is present. The claimed sequence SEQ ID NO:9 which consists only of 2kb is not necessary within the area associated with any type of cancer, including ovarian, bladder and colorectal tumor. Yet applicant has not shown that SEQ ID NO:9 region is associated with any type of cancer, including ovarian, bladder and colorectal tumor. Furthermore, the art teaches the contrary, i.e. not all types of cancer are associated with abnormality of the chromosome 20q13.2.

Art Unit:

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 10:00 am to 2:00 pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4227.

Art Unit:

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Paula.Hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless **the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122**. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

May 28, 1999

  
PAULA K. HUTZELL  
SUPERVISORY PATENT EXAMINER